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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/616,390

07/09/2003

Harold N. Trick

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72960

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08/17/2009

Casimir Jones, S.C.
440 Science Drive
Suite 203
Madison, WI 53711

EXAMINER

IBRAHIM, MEDINA AHMED

ART UNIT

PAPER NUMBER

1638

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/616,390	Applicant(s) TRICK ET AL.	
	Examiner Medina A. Ibrahim	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,7-9,14-23,26,29-38 and 40-42 is/are pending in the application.
- 4a) Of the above claim(s) 7,8,14,21,22,37 and 41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 9, 15-20, 23, 26, 29-36, 38, 40, and 42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's response filed 05/12/09 in reply to the Office action of 05/12/09 has been entered. The declaration of Harold Trick under 1.132 has been considered.

Claims 1, 7-9, 14-23, 26, 29-38, and 40-42 are pending.

Claims 7-8, 14, 21-22, 37, and 41 are withdrawn from consideration as being directed to the non-elected invention.

Claims 1, 9, 15-20, 23, 26, 29-36, 38, 40, and 42 are under examination.

All previous objections and rejections not set forth below have been withdrawn in view of Applicant's amendment and/or upon further consideration.

Claim Rejections - 35 USC § 103

Claims 1, 9, 15-20, 23, 26, 29-36, 38, 40, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over each of Tobias et al (WO 01/37654) and MUSHEGIAN et al (WO 01/96584) in view of Zipperlen et al (The EMBO Journal (2001), vol. 20 (15), pp. 3984-3992). The rejection is repeated for the reasons of record as set forth in the last Office action of 11/12/08. Applicant's arguments and the declaration of Dr Harold Trick filed 05/12/09 have been considered but are not deemed persuasive.

Applicant alleges that the Examiner has not provided clear articulation of the reasons why the claimed invention would have been obvious over the cited prior art. Applicant cites KSR International Co. v. Teleflex Inc., 550 U.S. , 82 USPQ2d 1385,

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1396. Applicant also alleges that no basis to support the statement that the embryonic lethal genes from *C. elegans* can be used to obtain embryonic lethal genes from *H. glycines* with a reasonable expectation of success has been provided by the Examiner.

These are not found persuasive for the following reasons: firstly, the MPEP section 2142 states that the focus when making a determination of obviousness should be on what a person of ordinary skill in the pertinent art would have known at the time of the invention, and on what such a person would have reasonably expected to have been able to do in view of that knowledge; regardless of whether the source of that knowledge and ability was documentary prior art, general knowledge in the art, or common sense. What follows is a discussion of the Graham factual inquiries. In this case, the Examiner has clearly applied the Graham factual inquiries by first determining the scope and content of the prior art; ascertaining the differences between the claimed invention and the prior art; and then resolving the level of ordinary skill in the art to establish a prima facie case of obviousness based the following reasons:

The prior art teachings:

Each of Tobias et al and Mush teach methods of inhibition of parasitic nematodes in a plant by transforming the plant with DNA sequences encoding a dsRNA that targets a substantially identical nematode endogenous gene or gene portion; said endogenous gene is essential in nematode growth, development, parasitism, and reproduction. Mushegian et al also teach the dsRNA is expressed in plant cells including root cells that are taken up by nematodes during feeding (see at least pages 6-7).

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The prior art suggestion: Tobias et al teach that the essential genes to be targeted have been isolated from parasitic nematodes *Heterodera* and *Meloidogyne* or the genes can be identified using sequence information from cloned *C. elegans* orthologs known in the prior art.

Motivation in the prior art: Tobias et al teach soybean cyst (*Heterodera glycines*) and root knot (*Meloidogyne incognita*) nematodes are the major source of economic loss and the importance of the use dsRNA technology which have been effectively and safely used to control plant pathogens such as viruses.

The teachings, suggestion, and motivation in the prior art as set forth above, would have led one of ordinary skill in the art at the time this application was filed to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention with a reasonable expectation of success. See the MPEP 2143.

The Declaration of Dr. Harold Trick has been considered. The declaration states a person of skill in the art would not have been motivated to use dsRNA that is specific to embryonic lethal phenotype genes because of the following prior art teachings. Urwin et al (2002) that discloses dsRNA specific to major sperm protein, had no effect on the development of *H. glycines*; and Fairbairn et al (2007) that teach when nematodes feed on plants that express dsRNA that has been identified as lethal, there was no lethal effect.

These are not found persuasive for the following reasons: firstly, Urwin et al (2003) teach direct ingestion of dsRNA by preparasitic juvenile cyst nematodes that lead to RNA interference but do not teach a transgenic plant/cell expressing dsRNA that

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target specific nematode lethal phenotype gene to control the nematode as required by the instant claims. Urwin states “[a]s expected, treatment with dsRNA corresponding to MSP transcript had no effect on parasitic development or sexual fate over 14 day”.

Secondly, Fairbain et al (2007) teach transgenic plants expressing dsRNA that silenced *MjTis11* gene in the feeding nematode. At the paragraph bridging pages 1531 and 1532, Fairbain et al states that further research is needed to increase both the level of silencing and to identify nematode genes whose silencing results in a lethal phenotype. Thirdly, the rejected claims require any embryonic lethal phenotype gene, which is indistinguishable from the embryonic lethal phenotype genes identifiable using the *C.elegans* genes and methods taught by Zipperlen et al, and as suggested by Tobias et al. Since Applicant’s claims fail to recite specific construct that would result in a lethal gene phenotype in the nematode, the cited Urwin and Fairbain do not support Applicant's position.

The declaration also states the following to support Applicant’s position: 1) *C. elegans* is free living organism while *H.glycines* is a parasitic organism; 2) none of the cited references teach specific constructs for targeting lethal phenotype genes in *H. glycines* or constructs that are orally active; and 3) there is no guidance in the cited references as to what *H.glycines* embryonic lethal phenotype gene constructs should be used and how it should be used.

These are not found persuasive for the followings reasons: firstly, while *C. elegans* is a free living organism and *H.glycines* is a parasitic organism, they are both nematodes. Secondly, conserved genes such as embryonic lethal phenotype genes are

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expected to often retain the same function in different nematodes. This functional equivalents has been demonstrated by transforming *C. elegans* with homologous genes from other nematodes. See for example, Kwa et al (1995). J. Mol. Biol. 3:246:500-510 and Redmond et al (2001) Mol. Biochem. Parasitol 112:125-131. Thirdly, the rejected claims do not recite specific constructs for targeting lethal phenotype genes in *H. glycines* or specific constructs that are orally active that would distinguish the claimed invention from the cited prior art. The claims are directed to a transgenic plant comprising a nucleic acid sequence encoding an orally active dsRNA targeting for inhibition a *H. glycines* embryonic lethal phenotype gene. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

See *In re Lindner*, 173 USPQ 356 (CCPA 1972) and *In re Grasselli*, 218 USPQ 769 (Fed. Cir. 1983) which teach that the evidence of unexpected results should be commensurate with the scope of the claims. In this case, Applicants' unexpected results is limited to transgenic plants comprising specific RNAi construct that targets *H. glycines* lethal phenotype genes comprising SEQ ID NO: 1, 9, or 18.

The following the claim amendments are suggests placing the application in condition for allowance.

In claims 1, 26 and 42, it is suggested that, ---wherein the embryonic lethal phenotype gene is selected from the group consisting of SEQ ID NO: 1, SEQ ID NO: 9, and SEQ ID NO: 18--- be inserted before the period.

In Claim 15, -----wherein the nucleic acid sequence is selected from the group consisting of SEQ ID NO: 6 and SEQ ID NO: 17----- is inserted before the period.

In Claim 23, it is suggested that “the vector of claim 15” be replaced with ---RNAi construct selected from the group consisting of SEQ ID NO: 6 or SEQ ID NO: 17; wherein the plant has nematode resistance--.

Cancel claims 7-8, 14, 21-22, 37-38, and 41.

Remarks

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571)272-0797. The examiner can normally be reached on M-TH 8:00 am to 5:30 PM, and every other Friday from 8:00 AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MAI
8/14/2009

/Medina A Ibrahim/
Primary Examiner, Art Unit 1638